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Washington, D.C. 20231

Charles W. Ashbrook
Assistant General Counsel, Pharmaceutical Patents
Warner-Lambert Company
Park-Davis Pharmaceutical Research Division
2800 Plymouth Road
Ann Arbor, MI 48105

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,681,893

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,681,893, which claims the human drug product LIPITOR® (atorvastatin calcium) and a method of use of LIPITOR®, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,213 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 1,213 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of July 18, 1997 (62 Fed. Reg. 38564). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2,057) + 184 \\ &= 1,213 \text{ days}\end{aligned}$$

Since the regulatory review period began (October 31, 1990), after the patent issue date (July 21, 1987), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor the 14 year limitation of 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.	:	4,681,893
Granted	:	July 21, 1987

Original Expiration Date¹ : May 30, 2006

Applicant : Bruce D. Roth

Owner of Record : Warner-Lambert Company

Title : Trans-6-[2-(3- or 4-Carboxamido-Substituted
Pyrrol-1-Yl)Alkyl]-4-Hydroxypyran-2-One
Inhibitors of Cholestrerol Synthesis

Classification : 514/422

Product Trade Name : LIPITOR® (atorvastatin calcium)

Term Extended : 1,213 days

Expiration Date of Extension : September 24, 2009

Any correspondence with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 308-6916
Attn: Special Program Law Office

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.



Karin Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

RE: LIPITOR® (atorvastatin calcium)
FDA Docket No.: 97E-0075